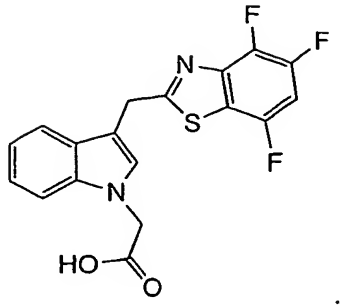
What is claimed is:

1. Hydrates of a compound of the formula:



2. A compound that is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate.

3. A pharmaceutical composition comprising an effective amount of a compound according to claim 1 or 2 and at least one pharmaceutically acceptable carrier, solvent, excipient or adjuvant.

4. A method of preventing or alleviating chronic complications arising from diabetes mellitus, which comprises administering to a mammal in need of such treatment an effective amount of a compound which is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid, or a pharmaceutically acceptable salt thereof, or a hydrate thereof.

5. A method according to claim 4, wherein the compound is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate.

6. A method according to claim 5 wherein the mammal is a human.

7. A method according to claim 5 wherein the complications are selected from the group consisting of diabetic cataracts, retinopathy, nephropathy and neuropathy.

8. A method according to claim 5 wherein the complications are diabetic cataracts or retinopathy.

9. A method according to claim 5 wherein the complications are nephropathy or neuropathy.

10. A method of treatment according to claim 5 wherein the therapeutically effective amount for oral administration is about 0.01 mg to 100 mg/kilogram of body weight per day.

11. A method of treatment according to claim 10 wherein the therapeutically effective amount for oral administration is about 0.025 mg to 15 mg/kilogram of body weight per day.

12. A method of treatment according to claim 11 wherein the therapeutically effective amount for oral administration is about 0.05 mg to 10 mg/kilogram of body weight per day.

13. A method of treatment according to claim 10, wherein the therapeutically effective amount for oral administration is about 0.05 mg to 2.5 mg/kilogram of body weight per day.

14. A method according to claim 5, wherein the effective amount of the compound is contained within a unit dosage form containing about 1 to 10 mg of the compound.

15. A method according to claim 14, wherein the unit dosage form contains between about 0.5 mg to 100 mg of the compound.

16. A method according to claim 15 wherein the unit dosage form contains about 1 mg to 50 mg of the compound.

17. A method according to claim 16 wherein the unit dosage form contains about 1 mg to 15 mg of the compound.

18. A method of reducing sorbitol in tissues comprising administering from about 0.05 to 0.5 mg/kg/day of a compound which is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid or a salt or hydrate thereof.

19. A methods according to claim 24 wherein the tissue is sciatic nerve, lens, retina, kidney cortex or kidney medulla.

20. A method of reducing fructose levels in tissues comprising administering from about 0.05 to 0.5 mg/kg/day of a compound which is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid or a salt or hydrate thereof.

21. A method of increasing myoinositol in tissues comprising administering from about 0.05 to 0.5 mg/kg/day of a compound which is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid or a salt or hydrate thereof.

22. A method of inhibiting the polyol-induced loss of nerve conduction velocity in the sciatic nerve comprising administering from about 0.05 to 0.5 mg/kg/day of a compound which is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid or a salt or hydrate thereof.

23. A method of reversing cataract formation comprising administering from about 0.05 to 0.5 mg/kg/day of a compound which is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid or a salt or hydrate thereof.

24. A method of preventing cataract formation comprising administering from about 0.05 to 0.5 mg/kg/day of a compound which is {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid or a salt or hydrate thereof.

25. A method according to claim 5 wherein the unit dosage form contains about 5 mg to 10 mg of the compound.

26. A pharmaceutical composition comprising {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate, lactose and polyvinylpyrrolidinone.

27. A pharmaceutical composition according to claim 26, wherein the composition is formulated into granules.

28. A pharmaceutical composition according to claim 27 wherein the granule size is less than 1.0 mm.

29. A pharmaceutical composition in tablet form comprising, by weight of the tablet, from about 5-75% of {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate, about 25-85% of lactose monohydrate, about 3-6% polyvinylpyrrolidinone, about 2-4% of croscarmellose sodium, and about 4-8% magnesium stearate.

30. A pharmaceutical composition in tablet form comprising about 50 mg of {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate, about 248 mg of lactose monohydrate, about 16 mg polyvinylpyrrolidinone, about 10mg of croscarmellose sodium, and about 6mg magnesium stearate.

31. A pharmaceutical composition in tablet form comprising about 200 mg of {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate, about 98 mg of lactose monohydrate, about 16 mg polyvinylpyrrolidinone, about 10mg of croscarmellose sodium, and about 6mg magnesium stearate.

32. A pharmaceutical composition in capsule form comprising about 200 mg of {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate, about 98 mg of lactose monohydrate, and about 16 mg polyvinylpyrrolidinone.

33. A pharmaceutical composition according to claim 32, wherein the capsule comprises granules of blended {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate, lactose monohydrate, and polyvinylpyrrolidinone.

34. A pharmaceutical composition according to claim 33, where the granules have an average size of about 1mm.

35. A process for preparing a pharmaceutical composition according to any of claims 29-34, comprising forming granules of blended {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate, lactose monohydrate, and polyvinylpyrrolidinone, where the granules have an average size of about 1mm.

36. A process for preparing a compound of claim 1, comprising forming a solution of {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid in acetonitrile and water, and subsequently allowing crystals of the compound of claim 1 to form.

37. A process according to claim 36, wherein the solution is heated.

38. A pharmaceutical composition in tablet form comprising about 20-30 mg of {3-[(4,5,7-trifluoro-1,3-benzothiazol-2-yl)methyl]-1*H*-indol-1-yl}acetic acid monohydrate, about 270-280 mg of lactose monohydrate, about 10-

20 mg polyvinylpyrrolidinone, about 5-15 mg of croscarmellose sodium, and about 3-10 mg of magnesium stearate.

39. A method normalizing sorbitol levels in tissues in a human patient, which comprises administering to a a patient in need of such treatment an effective amount of a compound according to claim 1.